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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,791	02/27/2006	Yorimasa Suwa	1254-0305PUS1	6478

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1647

NOTIFICATION DATE	DELIVERY MODE
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08/21/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/569,791	Applicant(s) SUWA ET AL.	
	Examiner Marianne P. Allen	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 23-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 23-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's arguments filed 5/12/08 have been fully considered but they are not persuasive.

Claims 1-8 and 10-22 have been cancelled. Claims 23-41 have been newly introduced.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 23-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 9 has been amended and claims 23-41 are newly introduced claims. The claims are directed to a screening method for substances by determining the presence or absence of any interaction with SEQ ID NO: 2 and variants thereof. The generic screening methods now claimed were not disclosed nor contemplated by the originally filed specification. The whole disclosure of the specification is directed to finding compounds that interact with SEQ ID NO: 2 and are antidiabetic substances. The claims as written and the specification do not disclose why one of ordinary skill in the art would want to screen for compounds that interact with SEQ ID NO: 2 but do not possess antidiabetic properties. The specification does not disclose what the

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usefulness of a compound that **does not** interact with SEQ ID NO: 2 would be nor why one would want to identify such a compound.

In addition, claims 9, 36, and 37 recite “addition” of amino acids. The specification does not disclose addition of 1-30, 1-10, or 1-5 amino acids. It discloses only deletion, substitution, and insertion of the named numbers of amino acids.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 23-31, and 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites “thiazolidine derivative.” The specification does not provide the metes and bounds of what compounds are embraced or excluded by this phrase. The claims clearly encompass more than pioglitazone, rosiglitazone, troglitazone, and ciglitazone (specifically disclosed embodiments, see page 9). There does not appear to be an art understood definition for these derivatives. It is unclear what compounds must interact with SEQ ID NO: 2 or its variants.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9, 23-27, 32-33, and 38-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Ota et al. (U.S. Patent Application Publication 20070105122 A1).

Ota et al. discloses SEQ ID NO: 12235 which is identical with instant SEQ ID NO: 2.

Ota et al. discloses screening assays of candidate compounds such as small molecules and proteins with the protein of SEQ ID NO: 12235. See at least abstract, claims, page 1189, and alignment below. The protein of SEQ ID NO: 12235 would inherently be capable of interacting with the thiazolidine derivative pioglitazone as it is identical to instant SEQ ID NO: 2. (See claims 9 and 32-33.) The candidate compounds are not disclosed as being antidiabetic agents. (See claims 40-41.)

Alignment of SEQ ID NO: 2 with Ota et al.

```
US-10-917-503-12235
; Sequence 12235, Application US/10917503
; Publication No. US20070105122A1
; GENERAL INFORMATION:
; APPLICANT: OTA, TOSHIO
; APPLICANT: ISOGAI, TAKAO
; APPLICANT: NISHIKAWA, TETSUO
; APPLICANT: HAYASHI, KOJI
; APPLICANT: SAITO, KAORU
; APPLICANT: YAMAMOTO, JUNICHI
; APPLICANT: ISHII, SHIZUKO
; APPLICANT: SUGIYAMA, TOMOYASU
; APPLICANT: WAKAMATSU, AI
; APPLICANT: NAGAI, KEIICHI
; APPLICANT: OTSUKI, TETSUJI
; TITLE OF INVENTION: PRIMERS FOR SYNTHESIZING FULL-LENGTH cDNA AND THEIR USE
; FILE REFERENCE: 084335/0123
; CURRENT APPLICATION NUMBER: US/10/917,503
; CURRENT FILING DATE: 2004-08-13
; PRIOR APPLICATION NUMBER: US/09/629,469
; PRIOR FILING DATE: 2000-07-28
; PRIOR APPLICATION NUMBER: JP 1999-248036
; PRIOR FILING DATE: 1999-07-29
; PRIOR APPLICATION NUMBER: JP 1999-300253
; PRIOR FILING DATE: 1999-08-27
; PRIOR APPLICATION NUMBER: JP 2000-118776
; PRIOR FILING DATE: 2000-01-11
; PRIOR APPLICATION NUMBER: JP 2000-183767
; PRIOR FILING DATE: 2000-05-02
; PRIOR APPLICATION NUMBER: JP 2000-241899
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; PRIOR FILING DATE: 2000-06-09
; PRIOR APPLICATION NUMBER: 60/159,590
; PRIOR FILING DATE: 1999-10-18
; PRIOR APPLICATION NUMBER: 60/183,322
; PRIOR FILING DATE: 2000-02-17
; NUMBER OF SEQ ID NOS: 19025
; SOFTWARE: PatentIn Ver. 2.1
; SEQ ID NO 12235
; LENGTH: 667
; TYPE: PRT
; ORGANISM: Homo sapiens
US-10-917-503-12235
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Query Match          100.0%; Score 3458; DB 5; Length 667;
Best Local Similarity 100.0%; Pred. No. 1.3e-292;
Matches 667; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
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Db      61 QYTGHVQQQDHHPSSQQGGGLHGIYLRAFCTGLDSVLQPYRQALLDLEQEFGLDPHLSIS 120

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Db      361 YLLGRGELFQAFIDTAQHMLKTPPTAVTEHDVNVAQFQSAHKVLLDDNLLPLLHLTIEY 420

Qy      421 HGKEHKADATQAREGPSRETSPREAPASGWAALGLSYKVQWPLHILFTPAVLEKYNVVF 480
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Qy      481 YLLSVRRVQAEHQHCWALQMRKHLKSNQTDKIKWRLRNHMAFLVDNLQYYLQVDVLESQ 540
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Qy      601 LGPLDERGAAQLSILVKGFSRQSSLLFKILSSVRNHQINSDLAQLLRLDYNKYTQAGG 660
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Qy      661 TLGSFGM 667
        |||||
Db      661 TLGSFGM 667
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Claims 9, 23-33, and 38-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al. (U.S. Patent Application Publication 20070224201 A1).

Wu et al. discloses tumor-associated antigen target (TAT) polypeptide SEQ ID NO: 4169 which is identical with instant SEQ ID NO: 2. Wu et al. discloses high throughput screening assays of candidate compounds such as small molecules and proteins with the protein of SEQ ID NO: 4169. The polypeptide being assayed can be immobilized on a microtiter plate. Any known assay techniques can be used. See at least abstract, claims, page 240-242, paragraphs [6695-96, 6702-6705], and alignment below. The protein of SEQ ID NO: 4169 would inherently be capable of interacting with the thiazolidine derivative pioglitazone as it is identical to instant SEQ ID NO: 2. (See claims 9 and 32-33.) The candidate compounds are not disclosed as being antidiabetic agents. (See claims 40-41.) With respect to claims 28-31, applicant's basis for these claims is Reference Example 1 and page 15. These disclosures are directed to the protein immobilized on a microtiter plate. As such, the teachings of Wu et al. are deemed to meet the limitation of these claims.

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Alignment of SEQ ID NO: 2 with Wu et al.  
US-10-529-351A-4169  
; Sequence 4169, Application US/10529351A  
; Publication No. US20070224201A1  
; GENERAL INFORMATION:  
; APPLICANT: THOMAS D. WU  
; APPLICANT: ZEMIN ZHANG  
; TITLE OF INVENTION: COMPOSITIONS AND METHODS FOR THE DIAGNOSIS AND  
; TITLE OF INVENTION: TREATMENT OF TUMOR  
; FILE REFERENCE: P5101R1-US  
; CURRENT APPLICATION NUMBER: US/10/529,351A  
; CURRENT FILING DATE: 2005-03-25  
; PRIOR APPLICATION NUMBER: PCT/US03/28547  
; PRIOR FILING DATE: 2003-09-29  
; PRIOR APPLICATION NUMBER: US 60/414,971  
; PRIOR FILING DATE: 2002-10-02  
; NUMBER OF SEQ ID NOS: 6355  
; SEQ ID NO 4169  
; LENGTH: 667  
; TYPE: PRT  
; ORGANISM: Homo sapiens  
US-10-529-351A-4169
```

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Query Match 100.0%; Score 3458; DB 5; Length 667;
 Best Local Similarity 100.0%; Pred. No. 1.3e-292;
 Matches 667; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy      1 MIHELLLALSGYPGSIFTWNKRSGLQVSQDFPFLHPSETSVLNRLCRLGTDYIRFTEFIE 60
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Db    121 HVNYFLDQFQLLFPSSVMVVVEQIKSQKIHGCILETVYKHSCGGLPPVRSALKILAVCH 180

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Qy    361 YLLGRGELFQAFIDTAQHMLKTPPTAVTEHVDVNAFQQSAHKVLLDDDNLLPLHLTIIEY 420
      |||
Db    361 YLLGRGELFQAFIDTAQHMLKTPPTAVTEHVDVNAFQQSAHKVLLDDDNLLPLHLTIIEY 420

Qy    421 HGKEHKADATQAREGPSRETSPREAPASGWAALGLSYKVQWPLHILFTPAVLEKYNVVF 480
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Db    421 HGKEHKADATQAREGPSRETSPREAPASGWAALGLSYKVQWPLHILFTPAVLEKYNVVF 480

Qy    481 YLLSVRRVQAEQLHCWALQMQRKHLKSNQTDIAKWRLRNHMAFLVDNLQYYLQVDVLESQ 540
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Db    481 YLLSVRRVQAEQLHCWALQMQRKHLKSNQTDIAKWRLRNHMAFLVDNLQYYLQVDVLESQ 540

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Db    601 LGPLDERGAAQLSILVKGFSSRQSSLLFKILSSVRNHQINSDLAQLLLRLDYNKYTTQAGG 660

Qy    661 TLGSFGM 667
      |||||
Db    661 TLGSFGM 667
  
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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. in view of the specification at page 15.

Wu et al. is applied as above but does not disclose assaying by surface plasmon resonance.

Page 15 of the specification discloses that surface plasmon resonance using platforms such as the Biacore 3000 would have been well known in the art at the time of the invention.

Wu et al. discloses that any assay technique could have been used. Therefore, it would have been obvious to assay for candidate compounds interacting with SEQ ID NO: 4169 of Wu et al. (identical to instant SEQ ID NO: 2) using surface plasmon resonance as this would have been a well known assay method at the time of the invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (571)272-0712.

The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa